EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 2 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Tamara Carter, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01661	
Sandra Childress, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01564	PAUL J. MICHAELS, M.D. JUNE 18, 2016
Marion Chrysler v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02060	
Melissa Sanders, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01562	
Ana Sierra, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01819	
Toni Hernandez v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02073	

Reported by:

Rebecca J. Callow, CSR, RPR, CRR

DEPOSITION OF PAUL J. MICHAELS, M.D.
THIS DOCUMENT RELATES TO GENERAL TESTIMONY
Austin, Texas
Saturday, June 18th, 2016
8:04 a.m.

Deposition of PAUL J. MICHAELS, M.D, pursuant to Notice held at the offices of Hissey Kientz, 9442 N. Capital of Texas Highway Building 1, First Floor Conference Room, Austin, Texas, before Rebecca J. Callow, Registered Merit Reporter, Certified Realtime Reporter, Registered Professional Reporter, and Notary Public in and for the State of Texas.

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INDEX

EXHIBITS

Page 6

(Witness sworn.)
MR. AYLSTOCK: Before we get started, Dave, I guess, I know there were some e-mails flying back and forth. To the extent that Dr. Michaels was withdrawn as a general expert, he's -- by my e-mails for cases where he's designated, our understanding is that he will be designated both as case-specific and generic in those and we're permitting you to take a generic general deposition of Dr. Michaels pursuant to the notices that you provided.
MR. THOMAS: Thank you.
PAUL J. MICHAELS, M.D.,
Called as a witness herein, having been previously duly sworn by a Notary Public, was examined and testified as follows:
EXAMINATION
BY MR. THOMAS:
Q. Good morning, Doctor.
A. Good morning.
Q. I introduced myself to you before the deposition. My name is David Thomas and I represent Ethicon.
You've given depositions before?
A. Yes.

Page 7

(Exhibit 1 marked.)
BY MR. THOMAS:
Q. Let me show you what I've marked as Deposition Exhibit No. 1. It's a notice of deposition for you in six cases in the pelvic mesh MDL.
Have you seen that notice of deposition before?
A. Yes.
Q. Did you bring anything with you in response to Schedule A attached to the notice?
MR. CURTIS: Doctor, before you answer, for the record, we filed written objections -- e-filed written objections to the documents listed in the attachment to the notice for his deposition in all of these cases. I didn't bring written objections to be made an exhibit, Mr. Thomas, but I wanted the record to include that.
And also, we provided, by electronic link, the documents that were on the reliance list for each of the cases to include the medical records, the deposition transcripts, and other materials provided the doctor. So you have those in that form.

Page 8

MR. THOMAS: Okay. And is that all the information that you produced pursuant to the notice of deposition?
MR. CURTIS: It's all that I produced. I think that there are other materials that have also been produced, but that's an explanation of why Dr. Michaels did not bring materials in paper copy this morning.
MR. THOMAS: Thank you.
A. I have a flash drive that has my CV and all the representative information that was included in Schedule A of this notice of deposition.
BY MR. THOMAS:
Q. Can I have that flash drive?
A. Yes.
(Exhibit 2 marked.)
MR. THOMAS: I've marked as Exhibit No. 2 the flash drive that Dr. Michaels just gave me.
BY MR. THOMAS:
Q. Without going into great detail, unless you can, is there anything on the Schedule A that you did not produce?
MR. AYLSTOCK: Just again to

Page 9

reiterate, we objected to form to a large portion of it --
MR. THOMAS: I understand. I don't want to spend my time going through each one of them to figure it out.
MR. AYLSTOCK: That's fine.
BY MR. THOMAS:
Q. And if there's something that you know of that you didn't produce, tell me. Otherwise, we'll get to it later.
A. Not that I'm exactly aware of.
Q. Okay. And that's fine. We'll figure that out, perhaps, as we go along.
Would you state your full name for the record, please?
A. Paul Joseph Michaels.
Q. And, Dr. Michaels, you are a medical doctor?
A. Yes.
Q. And what is your area of specialty?
A. Pathology. Specifically atomic and clinical pathology with a subspecialty in cytopathology.
Q. Have you been identified as an expert

Page 10

witness in the Ethicon Pelvic Repair System Products Liability Litigation?
A. Yes.
Q. And you're here to testify on behalf of the plaintiffs?
A. Yes.
Q. In six cases.
Who contacted you about this litigation?
A. I don't remember exactly the order of how I was contacted, but I believe it was Mr. Aylstock's firm.
Q. Okay. And what were you asked to do?
A. I was asked to serve as an expert with regards to the pathologic evaluation of the mesh specimens in these clients that had brought this lawsuit.
Q. The notice of deposition lists six cases in which you're prepared to give opinions in this MDL. Did you review other cases?
A. Yes.
Q. How many other cases did you review?
A. One or two.
Q. Okay. And did you decline to give opinions

Page 11

in those cases?
A. No.
One of them I did give an opinion. I just -- it's not on here. I think it's for later.
And then the other one I was told kind of halfway through that that I shouldn't work on the case anymore. I don't know what was happening to it, if they were withdrawing or settling. I didn't ask. I was just told on this case -- and I don't even remember the name -- don't work anymore on it.
Q. Do you know the names of the plaintiffs in those two cases?
MR. AYLSTOCK: And with regard to that, I'm going to object to the extent that he may have been a consulting expert on those cases, you're not entitled to know the names of those cases until the time -- such time as he's been disclosed as an expert in those.
MR. THOMAS: I can't know that, Bryan. Are you instructing him not to answer or what? I don't know.
MR. AYLSTOCK: With regard -- one of those cases is not mine, so for that, without his lawyer here, who -- and I can probably shed some

Page 12

more light to you off the record, yes, I would tell him not to answer that question.
MR. THOMAS: Okay. Again, I don't want to spend time discussing stuff. That's going to waste my time or we're not going to get any answers.
BY MR. THOMAS:
Q. Prior to your retention in this case, can you tell me something about your familiarity with pelvic mesh implants?
A. Well, as a pathologist, I've been exposed to these specimens over the last several years. So I've grossly examined them, microscopically examined them, prior to being involved in this litigation, and that was basically it.
Q. Has that been in your capacity as a pathologist associated with the hospital?
A. That's correct.
Q. And how many pelvic mesh explants have you as a pathologist analyzed prior to your retention in this litigation?
A. I would probably say somewhere around two dozen, maybe.
Q. Over what period of time?

Page 13

A. Seven, eight years, maybe.
Q. Do you recall any time where you as a pathologist have been asked to analyze pelvic mesh implants to determine the extent to which the mesh contributed to the pathology in the tissue that you analyzed?
A. Could you repeat that?
MR. THOMAS: Could you?
(The record was read as requested: "Do you recall any time where you as a pathologist have been asked to analyze pelvic mesh implants to determine the extent to which the mesh contributed to the pathology in the tissue that you analyzed?")
A. Well, I would say that as a pathologist, that's what you do on a day-to-day basis. Whether you're specifically asked by the submitting surgeon, a particular clinical question, that's what we do is analyze specimens and report their pathological significance.
So I would say that -- yes, that's part of my purview as a pathologist just with general specimens would be to answer those clinical

Page 14

questions, whether they're specifically asked or not.
BY MR. THOMAS:
Q. Prior to your retention in this litigation, have you written pathology reports which expressed opinions about the impact that the presence of polypropylene mesh may have played in the pathology of the tissue that you reviewed?
A. Well, with regards to impact, I would say if you were talking about a foreign body response, that is in relationship to the mesh, then yes.
Q. Anything other than commenting on the foreign body response due to the presence of the mesh?
A. Fibrosis, fat necrosis. Those are the main things that we address in pathology reports with regards to either mesh or any foreign-type material.
Q. Have you had any training prior to your work in this litigation concerning the impact of polypropylene mesh in tissue?
A. I wouldn't say I've had any specific training with regards to the polypropylene mesh in tissue and its reaction. But just as a general pathologist, within our training we are, I guess,

Page 15

taught and schooled with respect to foreign bodies in general.
Q. Have you ever authored any papers related to the impact of polypropylene mesh on tissue in the pelvic floor?
A. No, I have not.
Q. Have you ever conducted any research concerning the impact of polypropylene mesh on tissue in the pelvic floor?
A. No.
Q. Have you ever spoken or taught on the topic of the issue of the impact of polypropylene mesh on tissue in the pelvic floor?
A. No.
Q. When you were asked to assist the plaintiffs in this litigation, what did you do to prepare yourself for the work that you were going to do?
A. Well, I re-reviewed a lot of the general pathology of inflammation and foreign body granulomas reactions from several different textbooks and, I guess, online pathology sources.
I reviewed a lot of the literature that I came into contact with, either that was

Page 16

provided to me or when I did my own PubMed search with regards to mesh, polypropylene, transvaginal surgeries, et cetera, I came across a lot of articles that way. I read a lot of articles in that respect.
I was -- I asked for and was given some of the internal Ethicon documents with respect to the litigation and their research on mesh.
And I reviewed some depositions from different physicians that had been involved in the litigation prior to me being asked to be in the litigation, as well as some of their prior expert reports to get a general overview of some of the issues in the litigation. I would say those would be the main things.
Q. What prior expert reports did you review?
A. Reports I think by physicians Klausterhoften, Clinge, I believe, Iakovlev as well.
Q. Any other expert reports you recall reviewing?
A. Well, not in the beginning, no.
(Exhibit 3 marked.)
BY MR. THOMAS:
Q. Let me show you what's Deposition Exhibit

Page 17

No. 3, which is your expert report in the Childress case. The expert report in the Childress case has a heading, "Background," "Summary of Opinions," and "Comment."
I'm interested now in the Comment section of Exhibit No. 3.
Does the Comment section in Exhibit No. 3, which goes from pages 2 through 5, does that generally represent your general report in this case?
A. I would say that that generally represents my general opinions with regards to the case, yes.
Q. Okay. And without showing you the other five reports, does -- can I use the Childress report as a template for your general opinions across all six cases?
A. I don't know about that, because I -- they change -- I can't remember specifically, as I sit here, but -- and without comparing all of the reports to one another, there may be some differences from one report to another to this comment section.
Q. Okay.
(Exhibit 4 marked.)

Page 18

BY MR. THOMAS:
Q. Let me show you what's been marked as Deposition Exhibit No. 4.
Deposition Exhibit No. 4 is Exhibit D that I was provided Thursday afternoon and represented to be your reliance list in connection with your opinions in this case.
A. I don't think so, because this one says "Chrysler deposition" on page 5, and we're talking about Childress.
Q. Well, the reason why I say that -- well, this was given to me by plaintiffs on Thursday afternoon.
Other than the page 5, which are individual medical records I think you said for the Chrysler case, do the first four pages of that Exhibit No. 4 represent your reliance materials for your general opinions in the case?
A. I believe so, yes.
Q. And you said a minute ago that you obtained these materials from a variety of sources.
Do you know which of these literature references you obtained on your own?
A. I couldn't go through them and pick them

Page 19

out.
Q. Counsel supplied you selected literature?
A. Initially, yes.
Q. Are you able to identify from materials that you have in your files those materials that counsel provided to you?
A. No. Because I put them all in one general folder.
Q. And likewise, are you able to identify those materials that you found on your own through your own PubMed search?
A. No.
Q. I believe you said you did some Internet research.
A. Well, with regards to general -- I mean, PubMed is an Internet research, so yes, I did.
Q. Did you do any -- what did you search for under PubMed?
A. Transvaginal mesh, you know, mesh pain, mesh complications, a variety of different -- I mean ...
Q. Other than your PubMed search on the Internet, did you conduct any other Internet research?

Page 20

A. Well, for general pathology, background information with regards to maybe some of the later advancements with regards to inflammatory cytokines and mechanisms that maybe were even more recent than the most recent textbooks I have on the subject, but not much in addition to that.
Q. And what did you search for specifically in your Internet research?
A. Inflammation mechanisms, foreign body response, pathology foreign body response, histology, biology, et cetera.
Q. You mentioned that you studied papers related to the complications associated with mesh in the pelvic floor.
Why was that important to you?
A. Because as part of my role as an expert, I am correlating the findings based on the literature with respect to histopathologic features that I'm finding in the mesh explants.
So if there are studies done with respect to correlating these findings, it was important to me, as a pathologist reviewing the mesh, to be able to identify those and correlate them with the individual case-specific opinions, I

Page 21

guess.
Q. In analyzing the complications associated with the use of mesh in the pelvic floor, did you determine the rate of those complications in surgeries?
A. From what I read, the rates seemed quite variable from study to study.
And it would depend on what you were specifically looking at and what was really considered a complication, because that seems to also have changed with respect to how, for example, recurrence is classified.
Q. To the extent that you studied the rates of complications occurring from mesh in the pelvic floor, did you include those papers in your reliance list, which is Exhibit 4?
A. I included everything in my reliance list that I thought was pertinent to my opinions and that I felt like seemed to be a pertinent study.
Q. Are the rates of complications from the use of mesh in the pelvic floor pertinent to your opinions in the case?
MR. AYLSTOCK: Object to the form of the question to the extent that you're talking about

Page 22

mesh generally.
THE WITNESS: Can you repeat that question?
(The record was read as requested: "Are the rates of complications from the use of mesh in the pelvic floor pertinent to your opinions in the case?")
A. I don't think necessarily.
BY MR. THOMAS:
Q. Why do you say you don't think necessarily?
A. Well, I'm just -- because these are all -- I'm being involved in cases where the complication has occurred. So whether that occurs in 1 in 10,000 or 1 in 5, it doesn't matter. It occurred in this case.
So, although it's something that is a background information with respect to how common something is, I don't think in a particular case it changes any opinion that I would render.
Q. As a part of your work in this case, did you undertake to determine how complications which result from the use of mesh in the pelvic floor occur?

Page 23

THE WITNESS: Could you repeat that? Sorry.
THE REPORTER: No problem.
(The record was read as requested: "As a part of your work in this case, did you undertake to determine how complications which result from the use of mesh in the pelvic floor occur?")
A. Yes.
BY MR. THOMAS:
Q. And how did you do that?
A. By trying to read some of the literature regarding the complications.
Q. And did you seek to understand the risk of complications in the pelvic floor from non-mesh procedures?
A. I don't know what non-mesh procedures you're talking about.
Q. Do you know what a Burch colposuspension is?
A. So you mean -- so you mean general treatment for prolapse, et cetera, that's not mesh?
Q. Correct.

Page 24

A. Oh, okay. Yes.
Q. So you did seek to understand the complications that occur for the treatment of conditions in the pelvic floor that don't involve mesh?
A. Well, in many of the reports that I had, there were discussions regarding comparing the complications with mesh from complications of surgeries that were similar prior to or without the use of synthetic mesh.
Q. As a part of your work in this case, did you make a determination of whether complications were greater or fewer in surgeries using mesh for the treatment of stress urinary incontinence as opposed to procedures involving the Burch colposuspension?
A. Well, with respect to mesh versus non-mesh, yes.
Q. And what did you learn from your work?
A. That the complications from surgeries with respect to using synthetic mesh were greater.
Q. Is that for the treatment of stress urinary incontinence?
A. Well, I would say, in general, with respect

Page 25

to organ prolapse and stress urinary incontinence, my understanding from reviewing the literature is that the use of synthetic mesh resulted in an increased number of complications with respect to those types of surgical procedures compared to procedures where non-synthetic mesh was used.
Q. Okay. Specifically, did your review of the literature lead you to conclude that the risk of complications in the use of mesh for the treatment of stress urinary incontinence is greater than the risk of complications from non-mesh procedures used to treat stress urinary incontinence?
A. I would say my general opinion, as I sit here now, from what I recall would be yes. But I don't have a lot of those studies in front of me to look at their reported complication rates.
Q. Do you remember which studies you used in that regard?
A. With respect to the authors' names?
Q. Yes. Anything you can do to identify the study so I can find it.
A. I can go through my reliance list one by one.
Q. I don't want to do that. I'm just asking

Page 26

if you recall anything off the top of your head.
A. Well, for me to identify these number of studies, I would have to go through them because I reviewed so much literature in preparation for --
Q. I understand.
A. Okay.
Q. Do you agree that acute or chronic dyspareunia is a risk of non-mesh surgery of the pelvic floor?
MR. AYLSTOCK: Objection to form.
THE WITNESS: Could you repeat that?
(The record was read as requested:
"Do you agree that acute or chronic dyspareunia is a risk of non-mesh surgery of the pelvic floor?")
A. I would say it can be, yes.
BY MR. THOMAS:
Q. Do you agree that acute or chronic pain is a risk of non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. Acute or chronic pain, in general, or ...
BY MR. THOMAS:
Q. Yes.
A. Like in your head? Pain can be anywhere,

Page 27

so I don't -- that seems like a nonspecific question. I don't understand it.
Q. What I'm trying to understand is when a person has surgery in the pelvic floor for the treatment of stress urinary incontinence or pelvic organ prolapse whether acute or chronic pain is a potential risk from that surgery.
A. You can repeat the question all you want. But what I'm saying is, pain where?
Pain can occur anywhere in your body, so if you're going to ask me if pain is a complication of something, I need to know if you're talking about pain in a particular location.
Q. I'm sorry. I'll ask a better question.
Do you agree that acute or chronic pain in the pelvic -- strike that.
Do you agree that acute or chronic pain in the pelvic floor is a risk of non-mesh surgery for the treatment of pelvic organ prolapse and stress urinary incontinence in the pelvic floor?
A. Yes. I would say pain in the pelvic floor can be a risk.
Q. Do you agree that vaginal scarring is a potential risk of non-mesh surgery in the pelvic

Page 28

floor?
A. I would say that vaginal scarring is a potential risk.
Q. And do you agree that infection is a potential risk of non-mesh surgery in the pelvic floor?
A. Yes. I would say that infection is a risk of basically any surgery regardless of where it's at.
Q. And do you agree that urinary problems, be it urinary frequency, urgency, dysuria, retention, obstruction or incontinence, is a risk of non-mesh surgery in the pelvic floor?
THE WITNESS: I'm sorry. Could you repeat that?
MR. AYLSTOCK: Objection. Form.
(The record was read as requested:
"And do you agree that urinary problems, be it urinary frequency, urgency, dysuria, retention, obstruction or incontinence, a risk of non-mesh surgery in the pelvic floor?")
MR. AYLSTOCK: Objection. Form.

Page 29

A. I would agree that urinary problems can be a potential risk of surgery in the pelvic floor.
BY MR. THOMAS:
Q. Do you agree that organ or nerve damage are potential risks of surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. I would want to know what organs you're talking about that would be dysfunctional.
BY MR. THOMAS:
Q. Are there risks of injury to any organs in pelvic floor surgery?
A. I would say organs that are in that anatomic location.
Q. And the same with respect to nerves that are in that anatomic location.
A. Correct. Nerves that are in that anatomic location can potentially be injured during the surgery.
Q. Bleeding is a potential risk of non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. Bleeding is a risk for any surgery regardless of location.
///

Page 30

BY MR. THOMAS:
Q. Inflammation is a risk of non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. Inflammation is a general process, it's not really a risk.
BY MR. THOMAS:
Q. Inflammation happens in connection with non-mesh surgery in the pelvic floor. Do you agree with that?
A. Inflammation is a very broad subject. So whether you're talking about transient inflammation or acute inflammation or granulomatous inflammation, it's a very general term.
Q. All three of those that you just used are risks of surgery -- risks of surgery for non-mesh surgery in the pelvic floor, aren't they?
MR. AYLSTOCK: Objection. Form.
A. I do not think so. You don't have a foreign body granulomatous inflammatory response if you're not using a foreign body.
BY MR. THOMAS:
Q. To the extent there's sutures involved in this surgery, it's a foreign body.

Page 31

A. Well, sutures can be absorbable or nonabsorbable.
So if they're nonabsorbable, yes. If they're absorbable, once they're gone, no.
Q. Okay. Is fistula formation a risk of non-mesh surgery in the pelvic floor?
A. I would think that fistula formation could be a potential risk for non-mesh surgery in the pelvic floor.
Q. Are neuromuscular problems a risk of surgery -- non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. I don't know what kind of neuromuscular problems you're referring to.
BY MR. THOMAS:
Q. Are neuromuscular problems in the pelvic floor muscles a risk of non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Same objection.
A. I would say they can be a potential risk.
BY MR. THOMAS:
Q. Are neuromuscular problems in the lower extremities a potential risk for non-mesh surgery of the pelvic floor?

Page 32

MR. AYLSTOCK: Objection to form.
A. I would say they can be.
BY MR. THOMAS:
Q. And are neuromuscular problems in the abdominal area a potential risk of non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. I would say maybe the lower abdominal area it would be a potential risk.
BY MR. THOMAS:
Q. And is there a risk of one or more surgeries to treat an adverse event in non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. I would say that's a general risk of any surgery.
BY MR. THOMAS:
Q. And is there a risk of recurrence or failure in non-mesh surgery in the pelvic floor?
MR. AYLSTOCK: Objection to form.
THE WITNESS: Could you repeat that?
(The record was read as requested:
"And is there a risk of recurrence or failure in non-mesh surgery in the

Page 33

pelvic floor?")
A. Recurrence or failure of what?
BY MR. THOMAS:
Q. Whatever condition is being treated.
A. I would say that's a potential risk.
Q. And in non-mesh surgery in the pelvic floor using sutures or grafts. There's a potential risk of a foreign body response. Would you agree with that?
MR. AYLSTOCK: Objection to form.
A. What kind of grafts?
BY MR. THOMAS:
Q. Any foreign body that you're putting in -- into the body.
A. Is it biological or synthetic?
Q. Well, let's start with synthetic.
A. Well, synthetic, yes.
Q. What about biological? Is there a risk of a foreign body response to a biological graft?
A. I guess it would depend on the type of graft.
Q. And for the use of sutures and grafts in non-mesh surgery in the pelvic floor, is there a risk of erosion of those sutures or grafts?

Page 34

MR. AYLSTOCK: Objection to form. Completely vague.
A. It would depend on the exact type of surgery and where those grafts or sutures are.
BY MR. THOMAS:
Q. Is there a risk of contraction of or shrinkage of tissues in non-mesh surgery involving the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. Well, with respect to scars, you can have a contracture of a scar. I guess it just is different with respect to quality and quantity of the contracture.
BY MR. THOMAS:
Q. Let's go to Exhibit 3, please. In Exhibit No. 3 you discuss the issue related to pore size in mesh. Fair?
A. I would say in very vague terms, yes.
Q. What did you know about issues related to pore size before your work in this case?
A. Very little general information.
Q. What did you know before your work in this case?
A. That pore size varied based on the mesh.

Page 35

Q. Is that all you knew before your work in this case?
MR. AYLSTOCK: Objection to form.
A. And that there were differences with them. But I didn't know specific differences until I started reading the literature with respect to this litigation.
BY MR. THOMAS:
Q. Okay. After you began your work on this litigation and you reviewed the litigation -- reviewed the literature, what is the problem with pore size? What is the issue?
A. Well, I would say the main issue, from my point of view as a pathologist, is that the smaller the pore size, the less likely you can have adipose tissue infiltrate into those pores between the filaments, and so there's much more likely to have bridging fibrosis between the filaments which will make the mesh less pliable, firmer, and also create a microenvironment where it's basically a constricting compartment-type syndrome with respect to the tissue that's able to infiltrate and incorporate within the pores.
Q. Do you have an opinion about how large the

Page 36

pores should be?
A. I didn't specifically pay attention to numbers with respect to pore sizes.
Q. But, do you, as you sit here today, have an opinion about how large the pore needs to be so that these issues that you just identified with the pore size don't occur?
A. I just said that I don't have any specifics with regards to the numbers, the sizes of the pores.
Q. No matter what the size of the pore, in your opinion, is there still a risk of the issues you just described from the use of any mesh for the treatment of conditions in the pelvic floor?
MR. AYLSTOCK: Objection to form.
A. Well, I would say with regards to that question the keyword would be "any." So there could be any risk, it's just depending on the amount.
BY MR. THOMAS:
Q. What do you look for in pathology for evidence that pores in the mesh are causing a complication?
A. Well, under the microscope I would look at the tissue between the filaments which represents the pores, or the filament spaces which would

Page 37

represent the pores, and see what kind of tissue is between those and associated with those.
Q. What kind of tissue do you want to see to show that there are no complications?
MR. AYLSTOCK: Objection to form.
THE WITNESS: Could you repeat that?
THE REPORTER: Yes.
(The record was read as requested: "What kind of tissue do you want to see to show that there are no complications?")
A. I don't think there would be any tissue that would confirm that there are zero complications.
BY MR. THOMAS:
Q. Okay. Let me ask this question. I probably asked a bad question.
What tissue are you looking for to identify any risk of complications from pore size?
MR. AYLSTOCK: Objection to form.
A. Well, again, I would say if I'm looking at the tissue and the mesh, that there's a problem with the mesh. There was a problem that was identified by the clinician with that mesh, depending on the

Page 38

clinical scenario, of course, and this isn't an autopsy and I'm looking at mesh.

So I would say features that would be most commonly associated with better incorporation of mesh would be seeing abundant adipose tissue in between the filaments which would indicate that there would maybe be possibly less constriction within those pores.

THE WITNESS: Can we get some more water?

MR. AYLSTOCK: Sure.

MR. THOMAS: There's a refrigerator full of it.

MR. AYLSTOCK: And any time you want to take a break.

THE WITNESS: I'm fine.

(Pause in proceedings.)

THE WITNESS: All right. Thank you.

BY MR. THOMAS:

Q. In your general report, Exhibit No. 3, you also discussed issues of the weight of the mesh.

What is your criticism about the weight of mesh?

MR. AYLSTOCK: You mean page number 3?

Page 39

MR. THOMAS: Page 3, Exhibit 3.

A. Well, as I stated, mesh that has a lighter weight has better tissue integration with less inflammation and scar formation, and is more likely to remain more pliable over time than a heavier-weight mesh.

BY MR. THOMAS:

Q. Are those statements in your report that you just referred to, are those based on your review of the literature or based upon your own experience?

A. Based on my review of the literature.

Q. You've not done a comparative study of different weight meshes to see how they perform in the pelvic floor. Is that fair?

A. That's correct. I have not done my own study.

Q. And you've not done any kind of study on your own to determine how different pore sizes perform in the pelvic floor. Is that correct?

A. That's correct.

Q. You also discuss in your report the risk of a condition known as contracture. What is contracture?

A. I don't know if I would call it a

Page 40

condition. It's more of a consequence or a finding where based on typically scar formation, you have a contracture or compression or shrinking, so to speak, of tissue where it comes together, is firm and, I guess, less mobile.

Q. Again, is this an issue that you learned from the literature or an issue that you learned about from your own experience?

A. About contracture in mesh? Or contracture in general?

Q. Contracture in mesh.

A. Well, I would say both. I would say my experience as a pathologist when I've examined mesh as a day-to-day workload issue, you can see that it's not normal mesh and that it's crinkled and contracted, irregular, deformed. I would say all of those would correspond to that finding or consequence of contracture.

Q. Every time that you've looked at mesh in your work as a pathologist, has it been in a histopathological slide?

A. No.

MR. AYLSTOCK: Objection to form.

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Page 41

BY MR. THOMAS:

Q. Have you looked at any mesh other than mesh that had already been affixed in formalin?

A. Yes.

Q. Have you looked at pelvic floor explants -- analyzed pelvic floor explants before they've been fixed in formalin?

MR. AYLSTOCK: Objection to form.

A. Grossly, yes.

BY MR. THOMAS:

Q. Okay. And under what circumstances would you, as a pathologist, look at pelvic floor explants before they've been fixed in formalin?

A. When it comes from the surgeon and we examine it grossly before formalin's been added.

Q. You told me before that you think about over the last seven or eight years you've maybe looked at about two dozen pelvic floor mesh explants. How many times have those mesh explants been delivered to you without being placed in formalin?

MR. AYLSTOCK: Objection to form.

A. I don't know. I would say maybe half of the times that I initially examined them and then

Page 42

added the formalin to the container.
BY MR. THOMAS:
Q. Do you agree that when mesh that's been implanted in the pelvic floor is removed from the body that the tissues surrounding the mesh contract?
MR. AYLSTOCK: Objection to form.
A. I don't understand that question.
BY MR. THOMAS:
Q. Okay. You understand that when mesh is implanted in the pelvic floor that the tissue grows in through the pores of the mesh and -- grows through the pores of the mesh?
A. Yes.
Q. And then when mesh is removed, when the tissue and the elastins in the tissue are released from the body, that the mesh itself with the tissue then contracts before it's placed in formalin. Do you agree with that?
MR. AYLSTOCK: Objection to form.
A. I don't know that I would use the word "contract" in that -- I guess --
I guess I could say that it changes shape or maybe is deformed. But when I am thinking of -- when we're discussing contracture, I'm

Page 43

thinking more of the pathophysiologic fibrosis that draws the tissue together. But does it change shape after its out of the body artifactually based on the circumstances that it was in both in vivo and then outside? Yes.
BY MR. THOMAS:
Q. Okay. And why does that happen?
A. Well, that happens with almost any type of specimen, that when you remove it, there is a change in the way the tissue is laying, in the way the tissue is shaped. And it's because in the body when -- before a particular type of tissue, whatever it is, is removed, it's within a structural framework. And once you remove that structural framework, there are natural consequences to taking that out and it no longer looks the same as when it was in the body.
Q. And when you then take the explant and place it in formalin, you understand that formalin reacts with the proteins on the mesh to fix the specimen.
A. The proteins that are in the tissue, the tissue changes predominantly, and that's with any tissue in formalin, yes.

Page 44

Q. And you understand that formalin fixation will cause excised tissue to contract due to the cross-linking of the proteins and the collagen?
MR. AYLSTOCK: Objection to form.
A. I haven't specifically read those details about mesh and formalin fixation and, quote/unquote, "contracting."
BY MR. THOMAS:
Q. Do you have reason to disagree with that statement?
A. Well, I would have to see the data and the studies that have -- the biochemical studies. I'm not, you know, a polymer scientist, so I don't have all those studies off the top of my head.
Q. As a part of your work in this case, have you analyzed how various meshes are implanted in the body?
A. I would say generally speaking.
Q. And how did you familiarize yourself with the mesh implantation process?
A. I watched some videos. I know from my own experience as a physician, both in medical school and doing internships, I've witnessed some of these types of procedures during urology.

Page 45

I would say kind of over the years I have had different experiences that have familiarized myself with those types of surgical procedures.
Q. Do you remember the videos you watched?
A. I don't remember the specific videos.
Q. I didn't see them on your reliance list.
A. Well, I didn't also put my urology rotation in medical school on my reliance list, but that's --
Q. But you've reviewed these videos in connection with your work in this case, didn't you?
MR. CURTIS: Objection. Let him answer.
A. Yeah.
So no. In the past -- I would say in the past and in connection with this case, there are several different types of experiences that I've had that have formed my, I guess, familiarity with the procedures.
BY MR. THOMAS:
Q. Have you familiarized yourself with the mesh removal process?
A. I would say that mesh is removed in different ways, so I don't know if there is an exact

Page 46

process of how a mesh, from one patient to another, is removed.
Q. Fair enough.
Have you made any attempt to study the different ways that mesh may be explanted from the pelvic floor?
A. I don't really understand that question. That's like -- I don't understand that question.
Q. What don't you understand?
A. Well, it's like asking me have I studied the ways that I can walk from point A to point B.
It depends on how mesh is removed; it depends on where it is in the body, and what vital structures it's next to. And if it's eroded into the rectum, has it eroded into the vagina? Has it eroded into the urethra? Has it eroded into the bladder? Has it ruptured a vessel?
I mean, how it will be removed surgically, even though I'm not a surgeon, it's clear that it would be completely based on the anatomic location that mesh had eroded into.
Q. In connection with your work on the six cases for which you've given opinions in this litigation, have you studied the methodology used by

Page 47

the surgeon to remove the mesh?
A. Well, I read the operative reports.
Q. Anything else?
A. Not that I can recall, other than reading the operative reports that were associated with the procedures.
Q. Doctor, do you consider yourself knowledgeable about the pathology slide preparation process?
A. I would say I have a general knowledge, but I don't participate in that as a pathologist.
Q. Have you ever, yourself, processed histology slides from pathology?
A. Processed in what respect?
Q. Put the tissue in a paraffin block.
A. I've put the tissue in the block and then I have loaded the cassettes in the past into the processor and taken them out, but I've never actually inserted the paraffin into the block once the tissue has been finally processed.
Q. Do you do the microtoming?
A. I have in the past.
Q. Is that something you typically allow others to do now?

Page 48

A. Well, we want others to do them; not that I allow them.
Q. Why do you want others to do them?
A. Because that's what they do for a living and my focus is diagnostics.
Q. Have you studied the effect of the slide preparation process on the polypropylene mesh in the slides that you looked at in this litigation?
A. I reviewed some studies that addressed both polypropylene material being -- maybe changes that occurred, or that were thought to have occurred because of the processing, and then other studies that looked at the polypropylene without any sort of processing. I've looked at, I think, both of those types of studies.
Q. Are those peer-reviewed studies or are those expert opinion reports?
A. I thought they were peer-reviewed studies.
Q. Would those studies be in your reliance list, Exhibit No. 4?
A. I don't know. I think so, maybe.
Q. Okay. And do you recall what you concluded from your review of the studies about any impact that the slide preparation process may have on the

Page 49

polypropylene that you analyzed in connection with these cases?
A. Well, my conclusion was that, based on what I was seeing and what you see in general under light microscopy, with regards to the characteristics of the polypropylene that it was not significantly influenced based on the processing.
Q. I believe you just told me it was based on your review of the slides. What I'm interested --
A. And the literature.
Q. And what I'm interested in is what did the literature tell you about the impact of the slide preparation process on the polypropylene that you were looking at in connection with these cases?
MR. AYLSTOCK: Objection to form. I think he's already answered that.
A. When I form an opinion it's based on everything, it's not based on just one thing. So I don't remember what I was specifically thinking when I was just looking at one or a couple of studies. But my general opinion with regards to that subject is what I just said.
BY MR. THOMAS:
Q. Okay. And when you say it's not

Page 50

significantly affected, do you have any opinions it affected at all?
MR. AYLSTOCK: Objection to form.
A. Well, I think the slide processing in pathology in general is, you know, a process that has gone on for years, and we know that it changes everything. It changes DNA, RNA, proteins; it changes antigen retrieval. But what is important is if there's any substantive changes to the tissues.
So, for example, if I'm looking at a breast cancer and it's been in formalin for a day, does that change the proteins of that cancer that it expresses? Yes. Does it change it to the respect that it would impact anything negatively or change anything in a clinically significant way? No.
And I would say the same thing with any type of tissue or synthetic material, that, you know, does the processing maybe change something at a molecular or biochemical level. I would imagine that it would. There's different chemicals that are being exposed to it, but does it make it look one way versus another? No. I would say, no.
BY MR. THOMAS:
Q. Does the microtoming process make the

Page 51

appearance of the tissue change from the way it was in vivo to the way it is under the slide?
MR. AYLSTOCK: Objection to form.
A. I would say the microtoming process can. But usually, as a pathologist, you can identify when there are folds in the tissue as opposed to something that is occurring biologically or pathologically.
BY MR. THOMAS:
Q. There are artifacts that can occur in the microtoming process that pathologists can detect.
A. That was a statement; are you asking a question?
Q. Yes.
Is that true?
A. So yes. In any type of specimen, there are artifacts that we can see and are comfortable usually identifying that are artifacts of the microtoming process and of the fixation process and of the staining process.
Q. Each one of those three is capable of producing artifacts, and it's the job of the pathologist to identify those artifacts and take those into consideration with your analysis. Is

Page 52

that fair?
A. Yes. I would say that's fair. We take all of that into consideration.
Q. Prior to your work in this case, had you read anywhere that as polypropylene mesh degraded in vivo?
A. You said "mesh"?
Q. Yes.
A. I don't recall seeing anything or having remembered reading anything about mesh, in general, that's derived from polypropylene, but suture material, yes.
Q. And when you talk about suture material, are you talking about polypropylene suture material?
A. Well, in general, yes.
I would say I've read about different types of both absorbable and nonabsorbable suture material and other types of material that can be implanted and how it degrades.
Q. Prior to your work in this case, what was your knowledge about Prolene mesh or sutures degrading in the body?
MR. AYLSTOCK: Objection to form.
A. Prolene, you mean like with a capital "P,"

Page 53

Prolene, from polypropylene or ...
BY MR. THOMAS:
Q. Correct. Prolene --
Did you know that "Prolene" is the brand name for Ethicon's polypropylene?
A. Yes. That's why I was clarifying.
I don't specifically remember seeing the brand name.
Q. What about polypropylene, generally? What is your recollection before this litigation about your knowledge of polypropylene mesh or sutures degrading in the body?
A. That the sutures can. That was before this litigation that they can degrade.
Q. In what context?
A. In what context "what"?
How does it happen?
Q. What do you remember that you read that the polypropylene sutures degraded?
A. I didn't read about -- I don't remember reading about the biochemical consequences or mechanisms, just that it can.
From a pathologist's point of view with respect to recognizing changes in the tissue,

Page 54

because we not infrequently will see suture material in all types of excisions.
Q. Prior to your work in this case, have you ever analyzed polypropylene mesh to determine the extent to which it may have degraded in the body?
A. No. I don't recall having done that before.
Q. Prior to your work in this case, have you ever analyzed polypropylene sutures to determine the extent to which they may have degraded in the body?
A. I would say I haven't analyzed them with respect to extent, just known that it occurs -- can occur after a period of time and will have seen suture material microscopically, but not more than that.
Q. And those times that you've just described, is that in connection with your work as a pathologist?
A. Yes.
Q. And do you remember the specifics of those circumstances where you recall seeing polypropylene sutures degrade?
A. They were in the setting of a prior abdominal surgery, from my recollection, and it was

Page 55

a re-excision of a tumor that had recurred. And there was a discussion in the past about -- this is more of an academic discussion about focusing on the suture material and the types of foreign body responses and what to look for as a pathologist, and what can be associated with them, et cetera.
Q. What conclusions did you reach about the use of polypropylene sutures in the body following that experience as a pathologist?
A. I wouldn't say there were any dramatic conclusions, just that it could degrade over time.
Q. And other than your work in this case, have you studied what are alleged to be the mechanisms of this degradation over time?
MR. AYLSTOCK: Objection to form.
A. With this case? Or litigation?
BY MR. THOMAS:
Q. Litigation.
A. Oh.
THE WITNESS: Can you repeat that?
THE REPORTER: Yes.
(The record was read as requested:
"And other than your work in this case have you studied what are alleged to

Page 56

be the mechanisms of this degradation over time?")
MR. AYLSTOCK: Same objection.
A. I don't know if I've specifically studied that. I mean, there have been probably basic general discussions about biologic mechanisms that contribute to degradation of foreign material in general, but I wouldn't say that I specifically analyzed those.
BY MR. THOMAS:
Q. If you go to page 5 of Exhibit No. 3.
A. Okay.
Q. And the paragraph beginning "Finally," you talk about degradation.
These are all -- strike that.
The papers and the documents that are listed in that paragraph, are those things that you reviewed in connection with your work in this litigation specifically. Is that fair?
A. They're some of them, yes.
Q. Okay. But there's nothing in paragraph -- in that paragraph that you had reviewed and read prior to the time of your work in this litigation. Is that fair?

Page 57

MR. AYLSTOCK: Objection to form.
A. Let me read the paragraph.
BY MR. THOMAS:
Q. I'm referring to the studies in the Ethicon documents themselves.
A. You're referring to what?
Q. Let me ask the question again, Doctor. I'm trying to make it simple.
In this paragraph on page 5 you list a number of papers. Correct?
A. Yes.
Q. Those papers were supplied to you by counsel as a part of your work in this litigation.
A. I don't know if all the papers were.
Q. Do you recall seeing any of those papers prior to your work in this litigation?
MR. CURTIS: I apologize. I'm confused. Are you talking about the Ethicon-only documents?
MR. THOMAS: I'm talking about the papers now. I haven't talked about the Ethicon documents yet.
MR. CURTIS: All right.
A. I don't recall.

Page 58

BY MR. THOMAS:
Q. Okay. What is the clinical significance of the degradation that you describe in paragraph -- in that paragraph on page 5 of the report?
MR. AYLSTOCK: Are you talking about the "Finally" paragraph?
MR. THOMAS: I'm talking about degradations.
BY MR. THOMAS:
Q. But let me ask it this way:
What is the clinical significance of what you describe as degradation in your report?
A. I would say the clinical significance with respect to degradation is that once you're degrading a foreign body and it breaks apart, there's a greater surface area now to that foreign body that's in connection and in affiliation with the tissue. So that would increase the inflammatory response, because now you have new foreign antigens that are in, I guess, direct contact with the tissue.
That would then increase the inflammatory response, and that increased inflammatory response would potentially or likely, given the severity of it, lead to additional damage

Page 59

to the remaining polypropylene or foreign material. And then that would then lead to more breakdown and more degradation, which would then turn into this, you know, basically cyclical phenomenon where you have a feedback loop that's just constantly going, contributing, to greater amounts of inflammation and scarring.
Q. Have you finished?
A. Yes.
Q. Okay. Can I limit the clinical significance that you identify from the degradation process that you describe to be an increased inflammatory response and increased scarring?
MR. AYLSTOCK: Objection to form.
BY MR. THOMAS:
Q. Those are the two things you just told me, I think.
A. Well, I said a whole paragraph, so ...
Q. I know. I was listening carefully. I thought you described each time those things: Increased inflammatory response, due to the cyclical nature of it, and then increased scarring because of the increased inflammatory response.
Is there anything else?

Page 60

A. Well, that would be, I guess, the pathological features which would correlate with other clinical symptoms.
Q. Okay. Let me ask it this way, then:
Is it fair to understand from your perspective as a pathologist that the significance of the degradation to you would be an increased inflammatory response and increased scarring?
A. I would say those would be the main things, yes.
Q. And however those manifested themselves in patients would be another issue?
A. Correct.
Q. All right. Are you aware of any scientific study published anywhere that describes the clinical significance that you've just related to degradation?
A. I've seen it described. It's not like I just made that up. So yeah. I have. I just -- I don't know -- I wouldn't know who's the author.
Q. Okay. Did you know this information or have this opinion prior to your work in this case?
A. Well, I would have that general opinion, but I hadn't specifically studied it prior to this

Page 61

case in the depth that I have, no.
Q. What is your knowledge of the extent to which -- strike that.
What is your opinion about the extent to which mesh implanted in the pelvic floor degrades? Is there a limit to it?
MR. AYLSTOCK: Objection to form.
THE WITNESS: Could you repeat that? I'm sorry.
THE REPORTER: Yes.
(The record was read as requested:
"What is your opinion about the extent to which mesh implanted in the pelvic floor degrades? Is there a limit to it?")
MR. AYLSTOCK: Same objection.
MR. CURTIS: Yeah. I'm sorry. I just don't understand the question. Go ahead.
A. Me neither. Yeah.
I would have to -- I don't understand what you mean by "a limit," so I don't understand the question.
BY MR. THOMAS:
Q. Okay. You've read Dr. Iakovlev's report.

Page 62

Correct?
A. Some of them.
Q. You know Dr. Iakovlev said that the outer core of polypropylene mesh degrades and then it stops. Do you know that?
MR. AYLSTOCK: Objection to form.
A. I don't specifically recall those words.
BY MR. THOMAS:
Q. Do you have any opinions suggesting that the degradation that you've studied and describe in your report on page 5 stops after a certain period of time?
MR. CURTIS: I don't know if it makes a difference. You repeatedly refer to that section -- "Comment" section in Exhibit 3 as his general report. I think his testimony was those pages contained his general opinions, not that it's his general report. That's a distinction he made.
MR. THOMAS: I'm not worried about that. If you want to make that distinction, that's up to you.
MR. CURTIS: No, no. I just want to make sure that when we're finished with the process, we all understand what you were after.

Page 63

BY MR. THOMAS:
Q. Is it your opinion that degraded mesh becomes embrittled?
A. Yes.
Q. Is it your opinion that degraded mesh forms cracks on the surface?
A. Yes.
Q. And is it your opinion that degraded mesh loses mechanical properties?
A. Yes. I would say all those are both my opinions and the opinions of the general medical literature.
Q. Have you ever studied the extent to which Prolene polypropylene embrittled over time?
MR. AYLSTOCK: Objection to form. Suture?
A. I don't ...
THE WITNESS: Could you repeat that?
THE REPORTER: Yes.
(The record was read as requested: "Have you ever studied the extent to which Prolene polypropylene becomes embrittled over time?")
A. Well, I would say with regards to study

Page 64

the -- I've studied it in the sense that I have examined it myself. So I would say, by definition, I'm studying it.
But with respect to the extent, I haven't done a comparison study with regards to other types of synthetic material and their embrittlement.
BY MR. THOMAS:
Q. Is it fair to say that the opinions that you have with respect to embrittlement and crack formation, based on work that you've done yourself, is your work in these cases?
A. No.
Q. What other work have you done to study the embrittlement and crack formation on Prolene polypropylene?
A. Well, the embrittlement is by my own examination of the gross specimens in the past. I didn't examine any of these specimens grossly.
So when I've -- you know, my experience, I guess, as a pathologist and a physician outside of the context of this litigation is -- is we've already discussed there are a couple of dozen cases where I've seen the mesh myself, and

Page 65

examined it, both in the context of prior to formalin fixation and after formalin fixation. And when I've examined those, those have been very stiff and rigid and sharp, and I would say that that contributes to my knowledge of that process.
Now, whether I've actually looked at them, you know, biochemically, no, I haven't. But, you know, studying them, I would say that my experience in the past would be characteristic of studying the material.
Q. Do you have available for us to analyze the pathology samples that you looked at over the past seven or eight years where you've reached these conclusions?
A. No.
Q. Do you have pathology reports for those two dozen or so times where you had the opportunity to analyze explants from the pelvic floor?
A. I don't have them myself, no.
Q. The last thing you say is the polypropylene -- excuse me -- that polypropylene loses mechanical properties. What mechanical properties are you referring to there?
MR. AYLSTOCK: Where are you at?

Page 66

MR. THOMAS: Right in the middle of the paragraph. "... embrittlement, crack formation, and loss of mechanical properties."
A. I would have to re-review that Clave article.
BY MR. THOMAS:
Q. Okay. As you sit here today, you don't know what mechanical properties?
A. Well, no. I'm using that as a general term, but not the specific mechanical properties other than their ability to perhaps be functional.
Q. Are you relying on the work of others to support your opinion that polypropylene that goes through a degradation process loses mechanical properties.
A. Not entirely, no.
Q. And what is your own experience that allows you to offer that opinion?
A. Well, because I have felt and know what the mesh feels like and functions like before it's implanted. I have felt it before and I've also felt it as a pathologist when it's come out of the patient. And it's in some of these cases that I have been aware of -- obviously, I don't examine all

Page 67

of these patients that don't have the mesh removed, and maybe some of them it stays relatively pliable. I don't know the extent.
But in the ones that I have examined, they are hard and don't move very much, and I would say that that is reflective of the fact that their physical and mechanical properties have been altered.
Q. Do you know which of the meshes that you've held in your hands following explant before fixation in formalin were Prolene meshes?
A. I would say, from my understanding, most of them were. But I don't know the percentage.
Q. And why do you say most of them were?
A. Because when I have these gross specimens with synthetic material or any type of foreign material, I make a habit of reviewing the operative reports to correlate what I'm seeing and what I'm not seeing, what I'm not submitting for histopathologic evaluation.
So in these operative reports they will discuss, this is this type, this is this type. You know, this is, whatever, Boston Scientific. You know, whether it's an implant for breast implant, et

Page 68

cetera?
So over time, I've become somewhat familiar with the different types even before this litigation. So that's why I said I would say most of them, but I didn't do a particular count.
Q. So to the extent that degradation associated with a mesh implant is causing clinical significance you would expect to find increased inflammation around that degradation. Is that fair?
MR. AYLSTOCK: Objection to form.
A. I would expect to see inflammation. Correct.
MR. AYLSTOCK: Dave, whenever you're at a good point, I could use a bathroom break.
MR. THOMAS: Let's take a break.
(Recess from 9:31 a.m. to 9:40 a.m.)
BY MR. THOMAS:
Q. Doctor, you told me earlier that you reviewed some information from Dr. Iakovlev.
A. Yes.
Q. Did you review expert reports from Dr. Iakovlev?
A. Yes.
Q. How many?

Page 69

A. One or two maybe.
Q. Did you review any depositions of Dr. Iakovlev?
A. Yes.
Q. How many?
A. I think two.
Q. Did you review any other documents from Dr. Iakovlev?
A. Just articles that he's published in the peer-reviewed literature.
Q. Do you still have the depositions that you reviewed of Dr. Iakovlev?
A. I would imagine they're on that flash drive.
Q. Okay. And do you still have the studies that you reviewed of Dr. Iakovlev?
A. Yes. Same thing. They're on the flash drive.
Q. They're not on your exhibit list or your reliance list. That's why I asked the question.
A. Oh, well, some of it I've gotten since I submitted my reports.
Q. We got an updated one Thursday.
A. An updated what?

Page 70

Q. Reliance list, Thursday.
A. I don't know.
Q. What have you gotten since you've submitted your reports that you've reviewed in connection with your work in this case?
A. Some of the client deposition transcripts.
Q. "Client" as in plaintiff deposition transcripts?
A. Yeah. Sorry. The plaintiff.
Q. We each have different clients.
A. Right. Sorry.
The -- some of the plaintiff deposition transcripts.
I've reviewed some of the defense expert reports.
I've reviewed probably some additional medical literature, just in general.
Q. Is Exhibit No. 2 a complete electronic file of the information that you've been provided and reviewed in connection with your opinions in the case?
A. It's as complete as I am aware.
Q. Okay. Was there any attempt by you to segregate out things from the electronic file,

Page 71

Exhibit No. 2, that you didn't produce to us?
MR. AYLSTOCK: Well, again, we've lodged our objections to a lot of the materials in there and you have those objections.
And you can ask the question.
A. I didn't catch the end of that question.
THE REPORTER: Do you need me to repeat it?
THE WITNESS: Yes, please.
(The record was read as requested:
"Was there any attempt by you to segregate out things from electronic file, Exhibit No. 2, that you didn't produce to us?")
MR. CURTIS: I don't even know what that means. Do you mean --
MR. THOMAS: He might be able to answer this question. If he can, he can answer it.
MR. AYLSTOCK: If you understand it, Doctor.
MR. CURTIS: I don't get "to segregate" from what? You know, are you asking --
MR. THOMAS: I'll start over again.
///

Page 72

BY MR. THOMAS:
Q. Did you give me everything you have, to the best of your ability?
A. Everything that my understanding was that I was supposed to provide you --
Q. Okay.
A. -- is on that disc -- or that USB, from my understanding.
Q. Are there any materials that you gathered yourself or you received from others in connection with your work in this case that you did not produce to us?
A. I don't know what types of materials those would be.
Q. As far as you know, you gave us everything that you either found yourself or that others gave you in connection with your work in this case?
A. That's my understanding.
Q. And for what purpose did you review the depositions of Dr. Iakovlev?
A. Well, they sent them to me.
And I said that I wanted to review them, because -- since he's a pathologist expert in this litigation as well, I wanted to see the types

Page 73

of questions that he was being asked.
And, you know, if there was something that surprised me about what they were asking, or something that I didn't think about that I should have evaluated or -- you know, I mean, I'm -- I'm a human being just like everybody else, so I can make mistakes, like anybody else.
And I thought, well, let me see if maybe he has a different understanding if he's asked a question, and I think, well, okay, this is how I would answer the question.
But then he answers it a different way. And then I have to think to myself, well, this is just in general. Well, am I thinking about it differently or is he thinking about it differently?
Let me go back to the literature on this point and see what the literature says.
So that was my intention when I -- any time I've reviewed deposition transcripts from any of the experts.
Q. And I believe you said you reviewed one or two reports of Dr. Iakovlev. Correct?
A. Correct.
Q. Do you know what cases they were?

Page 74

A. I'm not 100 percent sure, but I believe one of them maybe is Bellew or ...
Q. Good. Do you recall disagreeing with anything that Dr. Iakovlev said in his reports?
A. Not that I can recall.
Q. Do you recall disagreeing with anything that Dr. Iakovlev wrote in his papers that you have?
A. Again, not that I can recall.
Q. Okay. Have you ever met Dr. Iakovlev?
A. No.
Q. Have you ever spoken to him on the phone?
A. No.
Q. Have you spoken with any other pathologists who are looking at these types of issues in this litigation?
A. Not to my knowledge.
Q. Are you a neuropathologist?
A. I'm not board certified in neuropathology.
Q. What is a neuropathologist?
A. So the focus of a neuropathologist would be, I would say, central nervous system issues, generally, brain and spinal cord, and dealing with both the non-neoplastic and neoplastic entities that occur in that region.

Page 75

Some of them also do muscle biopsies and evaluate those, or large nerve biopsies and evaluate those for pathology. I mean, that's very neuropathologist-dependent because not all of them do that. I would say that's basically what they do.
Q. Did you consult with any neuropathologists in connection with your opinions in this case?
A. I didn't consult with any neuropathologists with regards to this case, no.
Q. Have you read any expert reports of neuropathologists submitted by Ethicon?
A. I believe so.
Q. Which ones have you read?
A. I don't recall the name. I think it was Hannes Vogel.
Q. The Stanford pathologist?
A. I think so.
Is he a neuropathologist?
Q. Yes, he is.
A. Yes. Then that's one of the ones that I can remember.
Q. Dr. McClendon?
A. I recall the name.
I've read so many of the defense

Page 76

expert reports, I can't remember who was who.
Q. Okay. Would those reports be on the thumb drive or the jump drive that you've given us?
A. I believe so. I don't know.
Q. Did you find yourself disagreeing with what Dr. Vogel said?
A. Well, I don't remember what -- exactly what he said, but -- and I don't remember which case it was in reference to.
Q. Okay.
A. But there were things that I remember thinking that it was -- I guess, the best word would be "petty."
Q. What did you think was petty about Dr. Vogel's report?
A. I can't remember if it was his report or not, but I believe it was his report that he talked about a figure of mine and said something like "Well, clearly his lack of experience is obvious because he didn't comment on nerve in this picture." Which I found to be so absurd and so petty and so ridiculous that I actually laughed out loud when I read it.
Because any time any pathologist puts

Page 77

any picture in any report, or whatever, in any figure in a peer-reviewed article or a figure in a text, we don't describe every single element of a picture and what's in there.
It's not a children's coloring book that I'm, you know, have a line and say, this is the hand; this is the arm.
Color the hand blue; color the arm white.
So I found that that was -- for him to point that out as evidence of my lack of experience with regards to nerves, I just -- I found that amusing.
Q. Anything substantive about his report that you disagreed with, that you recall?
MR. AYLSTOCK: Objection to form.
We can pull out the report if that's really what you're going to do, but this isn't --
MR. THOMAS: I don't want to go to that. I'm asking what he recalls.
MR. AYLSTOCK: And, as you know, his reports are case specific, so I'll remind you we have limited time for this general deposition.
MR. THOMAS: And you're using it right

Page 78

now.
MR. AYLSTOCK: And you're using it, and I'm pointing that out to you --
MR. THOMAS: Thank you.
MR. AYLSTOCK: -- as a courtesy.
MR. THOMAS: Thank you.
A. So I read his whole report. And, again, I don't remember -- I read so many of them, I don't remember the details of all of them without them in front of me. And I don't --
I think because that one comment about the nerve struck me as so funny that I don't remember other specifics about --
MR. AYLSTOCK: And if you'd like, we can get a printout of it and give it to you.
MR. THOMAS: I don't want that, Bryan. I'm just asking what he recalls.
A. I would say that's what I recall, as I sit here without it.
BY MR. THOMAS:
Q. Are you able to determine from the histology section under "Light Microscopy" whether nerve twigs that you see are sensory, motor, or autonomic?

Page 79

A. Well, most of them have sensory and motor functions, by definition.
Q. But are you able to discern from your review of the slide the extent to which there's sensory, motor, or autonomic?
A. So, from reviewing just a regular H&E slide, there's no way to tell with regards to sensory and motor.
Q. Or autonomic?
A. Right. Autonomic.
Q. Is there any stain that's capable of differentiating among nerves?
A. I don't use those stains on a day-to-day basis, so that's not something that I did in this litigation or have reviewed, because I don't -- I don't do that.
Q. Do you agree that the type of sensation that a nerve carries cannot be determined without identification of the sensory receptor that creates the signal?
THE WITNESS: Can you repeat that?
THE REPORTER: Yes.
(The record was read as requested:
"Do you agree that the type of

Page 80

sensation that a nerve carries cannot be determined without identification of the sensory receptor that creates the signal?")
A. I would say that sounds biologically correct.
BY MR. THOMAS:
Q. I'm not sure of the qualification. Why do you say "biologically correct"?
A. Because you're talking about a mechanism. So that's a biologic mechanism, and so I would say that sounds biologically correct.
Q. And is it fair to say that you need to identify the receptors to conclude that a given nerve fiber will transmit pain signals?
A. I don't know if that's true.
Q. Do you disagree with it or don't know if it's true?
A. I would say that I would say that more likely than not that that's not necessarily the case.
Q. Why?
A. Because these nerve bundles carry, as I said, both sensory and motor signals. So I don't

Page 81

think that you have to say -- I don't think you have to know the receptor to know for sure what kind of signal it's carrying.
Q. Do you agree that not all sensory nerve fibers transmit pain signals?
A. I would say that's correct.
Q. Are you suggesting by the reports that you've offered in these cases that you're able to diagnose disease by examining nerve twigs that you see in these slides?
MR. AYLSTOCK: Objection to form.
THE WITNESS: Could you repeat that?
THE REPORTER: Yes.
(The record was read as requested:
"Are you suggesting by the reports that you've offered in these cases that you're able to diagnose disease by examining nerve twigs that you see in these slides?")
A. I don't understand that question.
BY MR. THOMAS:
Q. Okay. Let me ask this question, and ask it the other way.
When you look at these slides, and you

Page 82

identify what you do, what is your purpose for these cases? What are you trying to do with what you reviewed from these slides?

MR. AYLSTOCK: Objection to form.

A. I would say my main purpose in reviewing these slides is to correlate my microscopic findings with the clinical indication for the surgical removal of the mesh. And to generate a pathologic differential diagnosis with regards to what the clinical indication was for the surgery and with what I'm seeing histologically and to rule out other causes that could have influenced the patient's infections or pain or dyspareunia, or whatever -- erosion, whatever else could have influenced that.

As a pathologist, that would be my main goal as to both correlate the findings that I'm seeing with what's described in the medical literature, as well as rule out other pathologic causes for those clinical symptoms and signs.

BY MR. THOMAS:

Q. What does the term "correlate" mean to you?

A. "Correlate" would be to take one set of findings with another set of findings and relate them to one another, I would say, would be a general

Page 83

definition that I would use.

Q. And in your work in this case, one set of findings is your findings from your review of the histologic slides. Correct?

A. That's correct.

Q. And what is the other set of findings that you're correlating with in order to give your opinion in this case?

A. Either the surgeon's findings operatively or the patient's symptoms or signs that have been described.

Q. And as a result of that, you then make a differential diagnosis as a pathologist as to the likely cause of the symptomology. Did I understand that correctly?

A. Yes. I would say that's fair.

Q. So you have control over the information that you review. You have a limited number of slides and you can look at it, and that's your set of findings. Correct?

A. Yes.

MR. AYLSTOCK: Objection to form.

BY MR. THOMAS:

Q. What do you do to make sure that you have

Page 84

all of the information from the rest of the findings in order to make the appropriate differential diagnosis?

A. Well, I mean, in addition to my slides, I would -- I'm not just reviewing them in a vacuum.

Q. I understand that.

A. So I review -- I ask for a full set of the medical records, and in some cases have asked if a deposition transcript for the plaintiff has been -- is available if I feel like there is any sort of inconsistency in the medical record, or something that isn't correlating with what the surgeon is reporting. Then I will ask for additional material.

But in these cases at least, I had extensive medical records that were just thousands and thousands of pages, so --

And it seemed to me from my review to be pretty complete, so as I went through them, for the most part, I think there may have been a couple cases where I specifically said, "Do you have this report?"

Or, "I don't have this operative report. Did you not send that?"

And, "Oh, well, actually, no. It's in

Page 85

this file folder, or maybe I missed it or something."

So there were times when I would call and say, "You know, I can't find this. Did you include this?"

Or, "You know, does this plaintiff have a deposition already? I'd like to review the deposition in this case."

Q. And all the information that you received for each of these six cases is on that flash drive that you supplied to us. Correct?

A. Yes.

MR. AYLSTOCK: Just so -- I think --

MR. THOMAS: Subject to the objections that you made.

MR. AYLSTOCK: Well, that, and I think you also have some Dropboxes that might be completely coextensive or not, but some links were provided last evening.

MR. THOMAS: Thank you for the timely production of the documents.

MR. AYLSTOCK: Same goes for you in every other deposition that I've been in. But I appreciate the compliment.

Page 86

BY MR. THOMAS:
Q. So what do you do to satisfy yourself that you have a complete set of information with which to do your differential diagnosis?
MR. AYLSTOCK: Objection to form.
A. Well, I'm a little uncomfortable by the verbiage of that question.
But -- I don't know what I do to satisfy myself that I'm okay with the information, but I basically review all of the -- once I have reviewed all of the data, all of the medical records, if I feel like I have a complete picture of what was going on clinically, then that's what I'm looking for.
BY MR. THOMAS:
Q. First of all, I don't mean to insinuate anything by my question. All I'm trying to understand is, at some point you become satisfied that you have what information you need to make a differential diagnosis.
And all I want to understand is how you go through that process to make sure you understand that you have what you need in order to make an appropriate differential diagnosis.

Page 87

A. Okay.
Q. That's all I intend with the question.
A. Okay.
MR. AYLSTOCK: And I think he's answered that extensively in what he's already said, so ...
MR. THOMAS: All I want to do is make sure he didn't think I was disparaging him in any way.
A. Oh, no.
BY MR. THOMAS:
Q. Do you rely on counsel to supply you with the information that you need?
MR. AYLSTOCK: With regard to the medical --
BY MR. THOMAS:
Q. With respect to the individual plaintiffs.
A. Well, yes. I don't contact the -- their -- it's not like I ask for a list of their physicians and contact the offices directly.
Q. Okay.
A. I rely on them to be responsive when I ask for medical records and further information.
Q. Did you have any help in reviewing the

Page 88

medical records, depositions or other information, related to these individual plaintiffs for the formation of your report.
A. I don't know what kind of help you're referring to.
Q. Well, you just described to me quite a volume of information. Did you do it all yourself?
A. I did it all myself.
Q. Okay. And for these six cases, about how many hours have you spent working on these cases?
A. Many, many, many hours. I don't have a number off the top of my head.
Q. Are your billing records included in what you've produced to us?
A. I'm not aware if they are or not.
Q. I know --
MR. AYLSTOCK: If they're not, I'll get them to you, Dave.
MR. THOMAS: Okay.
BY MR. THOMAS:
Q. How do you keep your time?
A. I have on my computer Word documents for each of the cases. And when I'm reviewing something, I have it on my drive -- my Google Drive,

Page 89

so if I'm in a library or wherever, at home, I look at what time I start and then when I'm done, I add that time.
Q. Okay. So real time as you're doing work, you update your individual time sheet for each case. Is that fair?
A. Constantly, yes.
Q. All right. And you have on your computer right now your up-to-date time that you spent on each of these six cases?
A. Yes.
Q. Do you maintain any other separate bill in addition to the six cases for which you're appearing here today for any general work you're doing on the file?
A. I think I have in the past, yes.
Q. Okay. So if I wanted to review the time that you spent on this matter, this litigation, it would be these six individual times, and then a general file or a general bill that would provide time that you spent there. Fair?
A. Yes. But having said that, I would also say that within the specific cases, there are times when I'm reviewing general information that relates

Page 90

to that particular case.
Q. Absolutely understand that.
A. Okay.
Q. Is there any other category of time for which you submit bills to the plaintiffs?
A. I don't think there's any other category of time that I submitted a bill.
Q. So if I get the bills for the six cases and the general file, I'll have a complete set of the bills and time that you've submitted to the plaintiffs in the case?
A. Yes.
Q. When you record your time as you do it, you record it by the amount of time you spent. Correct?
A. Correct.
Q. Do you describe what you were doing?
A. Yes.
Q. And what is your purpose when you describe what you're doing? What are you trying to say?
A. For my own recollection, mainly. It hasn't come up yet, maybe because it's not case specific.
But a lot of times I will be asked in depositions in the past, "When were you first contacted by the attorneys?"

Page 91

And I'll go to my invoice and say, this -- on such-and-such day, I had a ten-minute conversation with so-and-so.
And then "Well, when did you receive the slides?"
"Well, on such-and-such a day I received the slides and did an inventory."
So I do it for completeness' sake and to be able to give a good timeline if I'm asked.
Q. Okay. So the purpose of your time charges is not only to count your time but also to give you chronology so that you can recall what work you did at what time?
A. I'd say that's correct.
Q. In Exhibit No. 3, you discuss generally the concept or the idea of absorbable mesh on the first couple pages --
A. Okay.
Q. -- do you remember that? Under "Comment" on page 2.
A. Yes.
Q. Do you have any opinions that absorbable mesh should be used for the treatment of stress urinary incontinence?

Page 92

MR. AYLSTOCK: Objection to form.
A. I think I would leave as far as the actual material that needs to be used for these surgical procedures more to a surgeon.
I would say as a pathologist with regards to what type of material they should use -- whether it's synthetic, absorbable, nonabsorbable, biologic -- I would say I don't really have a general opinion about what is best surgically to use on these patients.
BY MR. THOMAS:
Q. Does that apply to both stress urinary incontinence and pelvic organ prolapse?
A. I would say yes, in general.
Q. Just so I can shut this down:
Is it fair to understand that you will not give any opinions at the trial in this case about the appropriate mesh material for the treatment of stress urinary incontinence or pelvic organ prolapse?
MR. CURTIS: Object to the form of the question. That's not what you asked him before.
MR. THOMAS: Sure, it is.
MR. CURTIS: You're talking about absorbable mesh and then you generalized and

Page 93

expanded the scope of it.
MR. THOMAS: He just -- I don't have real time. I'm sorry.
THE REPORTER: Do you want his last answer?
MR. THOMAS: I do.
"I think I would leave as far as the actual material that needs to be used for these surgical procedures more to a surgeon.
"I would say as a pathologist with regards to what type of material they should use, whether it's synthetic, absorbable, nonabsorbable, biologic, I would say I don't really have a general opinion about what is best surgically to use on these patients."
BY MR. THOMAS:
Q. And my question is, is it fair to understand that you're not going to give an opinion at trial in these cases about what material manufacturers should use in mesh for the treatment of stress urinary incontinence or pelvic organ prolapse in women?
MR. AYLSTOCK: Do you mean as opposed to the materials implanted in these women in the

Page 94

Ethicon mesh?
MR. THOMAS: That's what I'm trying to understand, Bryan. He told me no.
MR. AYLSTOCK: I'm trying to understand too. I'm not telling him not to answer, I'm just trying to understand what you're getting at.
A. So, I guess, to clarify, my opinion would be, as a pathologist, I'm not going to tell a surgeon, for this particular patient you need to use this material; for that patient you should use that material.
Oh, you need to make sure and go suburethrally with this type of material; go through the obturator foramen with this type of material.
That's not my goal or purview, I guess, as a pathologist. Mine would be to evaluate the types of material that I see pathologically and to correlate whatever histopathologic responses I'm seeing to whatever material with what's going on clinically.
BY MR. THOMAS:
Q. Do you have an opinion to offer in this case that the manufacturers should have used

Page 95

different material in any of the meshes you've analyzed?
A. I don't know about the specific types of material that was available to them. I didn't have those internal documents that I recall that specifically mention the different types of material that they could have used or how they advertised those materials. I don't have any of that information.
Q. I understand that.
Is it fair to understand that you're not prepared at trial to offer an opinion that Ethicon should have used a particular material in the -- in its meshes used for the treatment of stress urinary incontinence or pelvic organ prolapse?
MR. AYLSTOCK: Objection to form.
MR. CURTIS: Yes.
A. Well, you know, as a pathologist, the way I deal with -- or I guess, as any physician, the way I deal with questions that are medically related would be to answer the question that is posed to me.
So, I guess, with respect to your question, if I was asked at trial as a pathologist and in my opinion with the types of responses I've

Page 96

seen pathologically in this specimen, if there was another specimen type or another mesh type that was known to have these -- these characteristics that would not have given you the same -- that would likely not have given you the same pathologic response, would I feel, as a pathologist, that this type of material was better than another type of material? I would just answer any question as it's posed to me.
I don't know -- you know, when I'm asked, am I going to give this type of opinion in a court, I don't -- all I can say is I'm going to answer whatever questions I'm allowed to answer in a court, based on -- if I feel, based on my information that I have in the medical literature and what I've reviewed, that I can answer the question.
BY MR. THOMAS:
Q. For any of the six cases that you've reviewed and that we're here for the next two days, is there a different material that you would advocate for use of the treatment of stress urinary incontinence that would not produce the symptoms that these women experienced?

Page 97

A. Again, I don't -- I didn't discuss any use of a material that should have been used in contrast to what was used.
Q. Okay. And, as you sit here today, you don't have any opinions in that regard?
A. I haven't been asked any specific questions regarding that, and I haven't reviewed material with respect to that subject.
Q. Okay. Do you agree that it's a normal histological finding to see nerve branches in all types of surgically removed tissues?
MR. AYLSTOCK: Objection to form.
A. Could you repeat that, please?
BY MR. THOMAS:
Q. Do you agree that it is a normal histological finding to see nerve branches in all types of surgically removed tissues?
A. No.
Q. Why don't you agree with that?
A. Because it's not correct; that's why.
Q. Okay. Do you agree that surgical interruption of the microscopic nerve supply to all types of soft tissues in the human anatomy, whether in the presence of artificial materials or not, is

Page 98

always accompanied by fibrosis and the repair of blood vessels, nerve fibers, and other vital connective tissues?

MR. AYLSTOCK: Objection to form.

A. I would not say always with respect to any physiologic property in the body. But I would say that, more likely than not, different degrees of stromal reaction occur following those types of surgical procedures.

BY MR. THOMAS:

Q. Okay. What is the mechanism between, you know, inflammation that you describe in your reports and pain?

A. I would say the mechanism with regards to inflammation and pain is something that is extremely complex and not something that I, as a pathologist generally would report or describe.

Simply correlating the fact that inflammation is known to be associated with pain and reporting whether that inflammation is present or not, but not with regards to the receptors and the cytokines that are produced and the feedback loops and the cycles. That's not something that I have specifically reviewed in preparation for this.

Page 99

Q. Is it fair to understand that you can't tell me today the mechanism between inflammation and pain?

MR. AYLSTOCK: Objection to form.

A. No. I'm not saying -- what I said is that that mechanism is complex. And that --

BY MR. THOMAS:

Q. Can you explain it to me?

MR. AYLSTOCK: In how many hours?

A. Well, it's not -- it's that there --

Inflammation, depending on the inflammatory cell, whether it's a macrophage or a neutrophil, secretes different kinds of interlukens and cytokines, and those can cause other cells to migrate to the area. Those can induce fibroblasts proliferation, which in a more end stage, may entrap a nerve and cause pain that way.

Alternatively, if you have an eosinophil, which is another type of inflammatory cell, that secretes, say, Interleukin-5 or Interleukin-6 that can cause vasodilation of the vessels and cause edema to rush out into the tissue which gives you a pressure sensation which is painful.

Page 100

Neutrophils have different cytokines that can be secreted, and those can actually interact with the sensory receptors on the nerve itself which can give you a different quality of pain.

So when I say it's complex, it's because there's different types of pain and there's different types of inflammatory reactions that can produce those different types of pain.

BY MR. THOMAS:

Q. Finished?

A. Um-hmm.

Q. Thank you.

MR. THOMAS: Let's go back to his prior answer, please.

(Pause in proceedings.)

BY MR. THOMAS:

Q. I understood your prior answer to be that generally, you -- as a pathologist, you would not generally describe the mechanism of pain -- mechanism between inflammation and pain. Is that fair?

A. In a report.

Q. Okay. Is there a discipline within -- in

Page 101

medicine that is the appropriate discipline to discuss the specifics of the mechanism of inflammation and pain.

MR. AYLSTOCK: Objection to form.

A. I don't think that there's a specific discipline or specialty where that's their focus.

BY MR. THOMAS:

Q. Is there a discipline within medicine that has its focus that is more specialized than your own in this area?

MR. AYLSTOCK: In what area?

BY MR. THOMAS:

Q. In the mechanism between inflammation and pain.

THE WITNESS: Can you repeat that?

MR. THOMAS: I'll just ask it again.

THE WITNESS: Okay.

BY MR. THOMAS:

Q. Is there an area of medicine that is more specialized than your areas of expertise to explain the mechanism between inflammation and pain?

A. Well, I don't know if it would be in medicine or in biology. Because everything that I described is, you know, biological processes, which

Page 102

can occur in humans and animals.
So I would say that it's not necessarily in human medicine where any specialties focus on specifically inflammation and pain and those mechanisms that are causing them.
Q. Is it your testimony that you're as qualified in your discipline as any other discipline to offer opinions of the mechanism of inflammation and pain?
MR. AYLSTOCK: Objection to form.
A. I don't know.
BY MR. THOMAS:
Q. Okay. In your research in this case, did you make any effort to determine the existence of any studies that looked at the role of inflammation in mesh explants for patients who had mesh removed because of pain, as opposed to mesh removed for reasons other than pain?
THE WITNESS: Can you repeat that?
THE REPORTER: Yes.
(The record was read as requested:
"In your research in this case, did you make any effort to determine the existence of any studies that looked

Page 103

at the role of inflammation in mesh explants for patients who had mesh removed because of pain as opposed to mesh removed for reasons other than pain?")
MR. CURTIS: Object to the form of the of the question.
A. Yes. I did.
BY MR. THOMAS:
Q. Okay. Did you find any studies?
A. Yeah. There was a study that -- there was one study in particular that I reviewed. I can't remember the author's last name. I think it might have been Hill, or ...
Q. Yep.
That's not on your reliance list. Is there a reason why?
A. I tried to include everything on my reliance list that I had reviewed.
You know, again, not everything that's on there -- or not everything that is -- forms my opinions is on there, it just is the nature of my profession. But on this particular study, I thought that it was a really bad study.

Page 104

Q. So you chose not to deal with it.
A. No. I dealt with in the sense of I read it and I evaluated it. But from my recollection, there were a lot of problems with it.
Q. Okay. Do you remember generally what the problems were?
A. I think that it was -- I think it was a retrospective study, and I didn't feel like they -- it didn't seem like they could confidentially rule out that the patients that they were saying didn't have pain didn't actually have pain, because they were reviewing the records -- the medical records only, and there was no attempt to actually discuss these patients' reported pain or not, or had --
I should say had pain and just weren't reporting it because maybe they were so focused on their -- I think, it was urinary symptoms, which was the other group that had, like, urinary symptoms and supposedly not pain.
But I mean, I know patients in general will go to a physician and have several problems and report really one of them, and they may have another problem. But unless they are specifically asked may not report it. So that was one issue with the

Page 105

study.
Another one is they didn't really characterize the type of fibrosis or inflammation. They talked about grading it, like 0 to 3 or 0 to 2, I don't -- I know there were several different categories.
But they didn't really describe that in detail, like -- and the association with the mesh, whether that was inflammation around the mesh or it was away from the mesh.
And the reason that's important is because the specimens that would have been reviewed that were from around the bladder or around the urethra, that tissue, in general, can have some degree of inflammation that maybe would just be normal for that region, or could be normal for that region.
So if someone's not having pain, and they're saying, Oh, well, look, the patients that had no pain had just as much inflammation as the patients that had pain.
Well, you're not taking into account the fact that the patients that didn't have pain, their specimens were from areas that normally would

Page 106

have had more inflammatory cells, which is skewing the data. That was another problem that I had with that.

Just off the top of my head, those are the ones that I can remember.

Q. Sure. Any other studies that you looked at analyzing the role of inflammation in meshes explanted for reasons of pain and meshes explanted for non-pain reasons that you've looked at but haven't included in your report or your reliance list?

A. There may have been others. I just can't remember the specifics of the authors or the actual names.

Q. You agree that less than 5 percent of patients undergoing explantation of SUI slings do so for long-term pain, don't you?

MR. AYLSTOCK: Objection to form.

A. Would you repeat that?

BY MR. THOMAS:

Q. Do you agree of the patients who are undergoing -- well, strike that.

(Pause in proceedings.)

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Page 107

BY MR. THOMAS:

Q. For patients who receive mesh implants for treatment of SUI, do you know what percentage experience complications of pain more than six months?

MR. AYLSTOCK: Objection to form.

A. I guess I don't understand if you're asking pain greater than six months in duration or --

BY MR. THOMAS:

Q. Yes.

A. -- after six months.

Q. Six months greater in duration.

MR. AYLSTOCK: From the time of the original implant?

MR. THOMAS: Yes.

A. I don't understand.

So starting at six months and then have it for six months?

BY MR. THOMAS:

Q. No.

At the time of implant, pain persists from date of implant to longer than six months.

A. So --

Q. Are you aware of the number -- the

Page 108

percentage of complications -- the percentage of patients who receive mesh for stress urinary incontinence that experience mesh for -- pain for longer than six months?

MR. AYLSTOCK: Objection to form.

A. Again, I think that that's a very confusing question for me.

I don't really understand if you're asking from post-op day number one until post-op day number 180, or if they have six months of pain that may be on and off over the course of several years? I guess I just don't understand.

BY MR. THOMAS:

Q. That's fine.

You do agree that for more than 90 percent of the patients who receive mesh for the treatment of stress urinary incontinence they have no complaints of pain after six months?

MR. AYLSTOCK: Objection to form.

What kind of pain?

A. I -- I don't know. I don't understand.

BY MR. THOMAS:

Q. Have you studied the issue of pain as a complication in the use of mesh for the treatment of

Page 109

stress urinary incontinence?

MR. AYLSTOCK: Objection. Asked and answered. He's already --

MR. THOMAS: Please let me ask the questions completely, Bryan.

MR. AYLSTOCK: I objected to it.

A. Could you repeat that?

BY MR. THOMAS:

Q. Have you studied the extent to which pain is a complication in patients who receive mesh for the treatment of stress urinary incontinence?

A. Yes. I've reviewed the different complications from mesh.

Q. What are the rates of complications for pain over six months in women who've received mesh for the treatment of stress urinary incontinence?

MR. AYLSTOCK: Objection to form.

A. I don't know if you're talking about -- I don't specifically remember reading about studies that have looked at patients that have had six months of continual pain from the time of their surgery until six months post-op. I don't recall reading that data.

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Page 110

BY MR. THOMAS:
Q. Okay. And to the extent that you looked at studies in that regard, they'd be on Exhibit 2?
A. They should be.
Q. Okay. Do all women who receive mesh for the treatment of stress urinary incontinence have an inflammatory response to that mesh?
MR. AYLSTOCK: Objection to form.
A. I would say all women that have synthetic mesh implanted would have an inflammatory response to mesh.
BY MR. THOMAS:
Q. Why do some women experience pain and others do not?
A. I would say every human is different and there's a reason why complication rates aren't 0 percent verses 100 percent. It's because every body is different, every body has different responses, different genetics.
Maybe some people have a higher genetic predisposition to having a particular type of cytokine that's released.
Maybe some patients have other medical issues that would influence pain versus not pain.

Page 111

That doesn't take away from the fact that they're experiencing pain from a mesh.
So all of these factors influence whether someone has a particular type of symptomatology following any type of surgery.
Q. Did you review any studies analyzing the question why some women who receive mesh for the treatment of SUI, and who have inflammation, have pain and others do not?
A. Could you repeat that?
Q. Did you review any studies or papers of any kind which analyzed the question of why some women who receive mesh for the treatment of SUI experience pain and others do not?
A. Well, the first time you said "inflammation".
Q. What did I say the second time?
A. You didn't say "inflammation" the second time.
Q. Well, let me start over again.
What I'm trying to understand, Doctor, very simply: You gave me a descriptive answer about why some people experience pain and others don't.
Are you aware of any papers that

Page 112

discuss that issue specifically insofar as relates to the replacement of mesh for the treatment of stress urinary incontinence?
MR. AYLSTOCK: Objection to form.
A. I would have to go through my articles. I don't remember the specifics of your question in relationship to one particular article, but I would have to look at my different articles that I've reviewed.
BY MR. THOMAS:
Q. Okay. Fair to understand you don't recall one now?
A. I can't recall any of the specifics now, no.
Q. Is it true that chronic inflammation is a finding seen in the vaginal tissues of women suffering from stress urinary incontinence, pelvic organ prolapse, and other pelvic floor dysfunction even before mesh is implanted?
MR. AYLSTOCK: Objection to form.
A. I don't think that that's necessarily true, no.
BY MR. THOMAS:
Q. Okay. So --

Page 113

A. And it depends on the anatomic location.
Q. So if a woman has SUI, stress urinary incontinence, you would not necessarily expect to see inflammation if you did histology in the area of the SUI?
A. In what area of the SUI?
In the urethra? in the bladder? in the vagina?
There's a whole -- it's a completely different histology for all these locations.
Q. Are you saying there won't be any inflammation in some of these people who have these pelvic floor disorders?
A. Yeah. I would say if you took a vaginal biopsy in someone with SUI, I don't see why you would have inflammation.
Q. Okay.
A. If it wasn't otherwise inflamed by some other reason.
Q. Do you agree with this statement:
"At present, general human tissue interactions with the mesh are known, but we have an incomplete understanding of interactions specific to a mesh material and design as well as the

Page 114

pathophysiology of any complications"?
A. I don't understand that question.
MR. AYLSTOCK: Objection to form.
A. Or that statement. That seems very convoluted to me.
BY MR. THOMAS:
Q. Okay.
A. I'm not sure who wrote it for you but could you reread it.
Q. I didn't write it for me. But nobody wrote it for me.
"At present, general human tissue interactions with the mesh are known, but we have an incomplete understanding of interactions specific to a mesh material and design, as well as the pathophysiology of any complications."
A. I would say none of these processes are completely known 100 percent. There's always things that are discovered about the specific mechanisms of all these interactions. But that doesn't take away from the fact that we know a significant amount -- at least enough to know how certain material, like mesh, would interact in a patient's body.
Q. Do you agree with this statement:

Page 115

"That the question of whether polypropylene degrades in vivo has not been fully resolved despite decades of use"?
MR. AYLSTOCK: Objection to form.
A. Repeat that.
BY MR. THOMAS:
Q. The question of whether polypropylene degrades in vivo has not been fully resolved despite decades of use.
MR. AYLSTOCK: Same objection.
A. The polypropylene doesn't completely dissolve?
BY MR. THOMAS:
Q. Do you agree with the statement as I've read it?
A. Read it again.
Q. The question of whether polypropylene degrades in vivo has not been fully resolved despite decades of use.
MR. AYLSTOCK: Same objection.
A. I guess I don't know, because I would say it depends on the time. Because if it's -- maybe not fully with respect to maybe everyone, but I would say more likely than not after a significant

Page 116

amount of time, it would degrade. But I -- it would be something that you would have to evaluate microscopically.
MR. THOMAS: Let's go off the record for a second.
(Recess from 10:42 a.m. to 10:51 a.m.)
BY MR. THOMAS:
Q. Can you approximate how much time you've spent working on this litigation from the time you were retained till now?
A. Maybe -- I would say approximately 200 hours. Probably not -- maybe not that much. I don't know. 160 hours.
Q. And that would be for the six cases, as well as the general file for which you've billed time?
A. Correct.
Q. All right. And you charge $500 for your time?
A. Yes.
Q. And have you submitted bills yet?
A. Some.
Q. Have you been paid?
A. Some.

Page 117

MR. THOMAS: Pay his bills, Bryan.
MR. AYLSTOCK: You know, you keep me busy.
BY MR. THOMAS:
Q. And when -- what's your best recollection of when you were hired in this case?
A. I think there were some initial contact in January of this year, but I didn't receive slides or anything until well after that.
Because I know my reports were due in early May, and maybe I had slides for over a month before that or something.
Q. When did you begin your general literature review?
A. Probably in February, I would imagine. January, February.
Q. That would be reflected in your time charges?
A. It should be.
Q. Do you have privileges at hospitals now?
A. Yes.
Q. And which hospitals do you have privileges now?
A. Let's see. St. Davids Medical Center.

Page 118

Q. St. Davids?
A. Yes.
Seton Medical Center.
Q. Seton?
A. S-e-t-o-n.
It's all in the second paragraph of my ...
Q. It sure is.
Dell Children's Medical Center?
A. Um-hmm.
Q. Arise Austin Medical Center?
A. Arise (pronouncing), yeah.
Q. Westlake Medical Center?
A. Yes.
Q. Resolute Health Hospital?
A. Right. Seton Northwest.
Q. As a result of your work in this case, have you developed any concerns medically about the safe use of Prolene polypropylene in patients?
MR. AYLSTOCK: Objection to form.
A. I would say not from a pathologist's standpoint in my -- in my perspective, I guess, or from my perspective.
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Page 119

BY MR. THOMAS:
Q. As a doctor who has medical privileges at the doctors -- at the hospitals that you've identified on your report, have you developed any concern about the safe use of Prolene polypropylene in patients of those hospitals?
A. Well, I would say that's not really -- there is nothing that I have identified that I find to be influencing mortality or something that would be a significant alarm that I would raise with the medical staff.
Q. If you had identified any concern from your work in this case that you believe that PROLENE Polypropylene could not safely be used in patients at these hospitals, you would tell the medical staff, wouldn't you?
MR. AYLSTOCK: Let me object to the form.
As you know, Dave, a lot of this is off the market, so your question is entirely too broad.
A. Again, I -- from what I have experienced in my practice, there is nothing that I am seeing in my practice that I guess would relate to the current

Page 120

work that I'm doing as an expert witness that I have felt the need to go to the medical staff and say this has to never be used again.
BY MR. THOMAS:
Q. I need to ask the question a little more specifically.
A. Okay.
Q. Is it fair to understand that nothing in the work that you've done has caused you to believe that the use of Prolene sutures at the hospitals where you have privileges creates a danger in the people that receive those Prolene sutures?
MR. AYLSTOCK: Objection to form.
A. I would say from my standpoint, that's correct.
BY MR. THOMAS:
Q. Is it fair to understand that nothing that you've done in the work you've done in this case caused you to believe that the use of Prolene polypropylene in the mesh used in the treatment of stress urinary incontinence creates a danger to any of the women that received those meshes at the hospitals where you have privileges?
MR. AYLSTOCK: Let me object to the

Page 121

word "danger." I don't know what you mean by that.
A. Well, again, as I said, there's nothing that I would say is life threatening that would necessitate me as a pathologist, in my role at the hospitals, going to the medical staff to ensure that something is not used.
BY MR. THOMAS:
Q. Do you find from your work in this case that Prolene polypropylene and the meshes used for the treatment of stress urinary incontinence manufactured by Ethicon create an unreasonable risk of danger to women that receive them in the hospitals where you have privileges?
MR. AYLSTOCK: Objection to form.
THE WITNESS: Could you repeat that?
(The record was read as requested:
"Do you find from your work in this case that Prolene polypropylene and the meshes used for the treatment of stress urinary incontinence manufactured by Ethicon create an unreasonable risk of danger to women that receive them in the hospitals where you have privileges?")

Page 122

MR. AYLSTOCK: Same objection.
At what point in time? With what labels affixed? It's entirely too vague.
A. I guess I don't really -- I don't really understand the question.
BY MR. THOMAS:
Q. Is it true that you've not told anybody at the hospitals where you work that they should stop implanting Ethicon TVT meshes for the treatment of stress urinary incontinence? True?
A. That's correct.
Q. And the reason why you haven't done that is because you don't see that any of the Ethicon meshes used for the treatment of stress urinary incontinence present an unreasonable risk of harm to the women that receive them. Correct?
MR. AYLSTOCK: Objection to form.
A. No. I would say that's kind of an oversimplification of my role as a pathologist in the hospital.
My role would not be to alert the medical staff to stop using a particular type of medical device without knowing if there are risks that are now discussed with these patients may be

Page 123

what I consider to be dangerous, maybe a woman now after discussing those known risks with her physician wouldn't consider dangerous.
I would say my role as a pathologist would be that if I found that these were associated with a high risk of developing leukemia, and it's not something that's reported in the medical literature, and it's a product that's still being used.
Something like that at that point, I would go and sound the alarm to the medical staff that, Hey, this is something that is not described in their handouts. It's not something that's being discussed by the company. You haven't had the opportunity to discuss this risk with the patient. But my experience as a pathologist from reviewing X number of patients is that this is causing leukemia so you need to be aware of that.
There's no scenario like that that has occurred that I have felt the need to alert the medical staff, because the risk/benefit ratio of any procedure, whether I deem it dangerous or not, is not my responsibility given that that's what the surgeon discusses with the patients in their

Page 124

preoperative visits.
BY MR. THOMAS:
Q. Fair to conclude, though, that you have not had conversations with anybody on the medical staffs of any of the hospitals where you have privileges about any risks associated with the TVT devices for the treatment of stress urinary incontinence. Correct?
MR. AYLSTOCK: Objection to form.
A. I have not had any discussions with the medical staff about TVT or any sort of polypropylene-containing mesh.
MR. THOMAS: Okay. I think we're ready to go to individual cases.
MR. AYLSTOCK: Okay.
MR. THOMAS: Do you want to take a break first?
MR. AYLSTOCK: Yeah. Let's conclude the general deposition.
MR. THOMAS: And just for the record, we have an agreement that background questions and questions that we've asked in this general deposition will be applied to the individual cases so that we don't have to reask or redo certain

Page 125

things.
MR. AYLSTOCK: Yeah. In fact, we'll insist that it not be reasked or redone.
MR. THOMAS: Right.
MR. AYLSTOCK: Anything that was covered in the general portions of this report.
MR. THOMAS: But there will be times obviously where we will have to ask predicate questions in order to form an appropriate question, and we'll deal with those as they arise.
MR. AYLSTOCK: Mr. Curtis will deal with them.
MR. CURTIS: Well, the understanding is, the time we've just spent is on the general issues, and will not be repeated in the six individual cases.
MR. THOMAS: Well, as best we can, unless we have to relate it to a question in order to make the question clear. And we'll figure that out. I don't think we'll have any problem with that.
MR. CURTIS: I don't think we will either.
What's the time?

THE REPORTER: The total time is 2 hours, 36 minutes.
MR. CURTIS: Thank you.
(Proceedings concluded at 11:03 a.m.)

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ERRATA
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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
PAUL J. MICHAELS, M.D. DATE

Subscribed and sworn to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS PRODUCTS LIABILITY LITIGATION — Master File No. 2:12-MD-02327

THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 2 OF MDL 200:

Tamara Carter, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01661

Sandra Childress, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01564

Marion Chrysler v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02060

Melissa Sanders, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01562

Ana Sierra, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01819

Toni Hernandez v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02073

MDL 2327
JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

REPORTER'S CERTIFICATE
ORAL DEPOSITION OF PAUL J. MICHAELS, M.D.
June 18, 2016

I, Rebecca J. Callow, Registered Merit Reporter and Notary Public in and for the State of Texas, hereby certify to the following:

That the witness, PAUL J. MICHAELS, M.D., was duly sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness;

That the original deposition was delivered to _____.

That a copy of this certificate was served on all parties and/or the witness shown herein on _____.

That pursuant to information given to the deposition officer at the time said testimony was taken, the following the amount of time used by each party at the time of the deposition:

David B. Thomas (2h36m)
Attorney for Johnson & Johnson and Ethicon, Inc.

Bryan F. Aylstock (0h0m)
Attorney for Plaintiffs

I further certify that pursuant to FRCP Rule 30(f)(1) that the signature of the deponent:

[ ] was requested by the deponent or a party before the completion of the deposition and is to be returned within 30 days from date of receipt of the transcript. If returned, the attached Changes and Signature Page contains any changes and the reasons therefor;

[ ] was not requested by the deponent or a party before the completion of the deposition.

I further certify that I am neither counsel for, related to, nor employed by any of the parties or attorneys to the action in which this proceeding was taken. Further, I am not a relative or employee of any attorney of record in this cause, nor am I financially or otherwise interested in the outcome of the action.

SUBSCRIBED AND SWORN TO under my hand and seal of office on this the _____ day of _____, _____.

_____
Rebecca J. Callow, RMR, CRR, RPR
Notary Public, Travis County, Texas
My Commission No. 12955701-3
Expires: 09/12/2017